NOV 0 7 2001

K 012598

SECTION 2. SUMMARY

A. 510(K) SUMMARY

Submitter: SterilMed, Inc.

Contact Person: Patrick Fleischhacker
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Date Prepared: August 8, 2001

Trade Name: Reprocessed Laparoscopic Electric Instruments

Classification Name: and Number: Endoscopic Electrosurgical Accessory
Class II, 21 CFR 878.4400

Product Code: GEI

Predicate Device(s): The reprocessed laparoscopic electric instruments are substantially equivalent to Evershears® Scissors, BiLap®Probes, BiCoag® Forceps (K945975), manufactured by Everest; Tripolar® Cutting Forceps (K932293), manufactured by Circon; Endopath® Endoscopic Instruments (K984240), manufactured by Ethicon; and the counterpart devices from the original manufacturers.

Device Description: Laparoscopic electric instruments are devices that are designed for use via laparoscopes or open surgical procedures. The devices have a handle, a rotating insulated shaft with a diameter range of 3-15mm, a length of 15-45cm, and a distal cutting tip. The distal end of the device consists of a variety of distal end configurations including: dissectors (straight or curved), extractors, graspers, endosonic scissors (curved, hooked, or metzenbaum), shears, and cutting or dissecting forceps. The devices may be monopolar, bipolar, or tripolar and have a cautery connector that extends from the top of the handle. The device is connected via a cautery cable to a RF generator which provides electrical current to the device. This submission is for the instrument itself and does not include the cautery cable or generator.

Intended Use:

Laparoscopic electric instruments are designed for use in minimally invasive procedures and open surgical procedures to facilitate coagulation, transection, resection, mobilization, and dissection of tissue.

Functional and Safety Testing:

Representative samples of reprocessed laparoscopic electric instruments underwent bench testing to demonstrate appropriate functional characteristics. Process validation testing was done to validate the cleaning and sterilization procedures as well as the device's packaging. In addition, the manufacturing process includes visual and functional testing of all products produced.

Conclusion:

The reprocessed laparoscopic electric instruments are substantially equivalent to Evershears® Scissors, BiLap®Probes, BiCoag® Forceps (K945975), manufactured by Everest; Tripolar® Cutting Forceps (K932293), manufactured by Circon; Endopath® Endoscopic Instruments (K984240), manufactured by Ethicon; and the counterpart devices from the original manufacturers.

This conclusion is based upon the devices' similarities in functional design, materials, indications for use, and methods of construction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 0 7 2001

Mr. Patrick Fleischhacker
Vice President of Regulatory and Quality
SterilMed, Inc.
11400 73rd Avenue North
Minneapolis, Minnesota 55369

Re: K012598
Trade/Device Name: Reprocessed Laparoscopic Electric Instruments
Regulation Number: 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 8, 2001
Received: August 10, 2001

Dear Mr. Fleischhacker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Walker, MP

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use Page

Device Name: Reprocessed Laparoscopic Electric Instruments

Indications for Use: Laparoscopic Electric Instruments are designed for use in minimally invasive procedures and open surgical procedures to facilitate coagulation, transection, resection, mobilization, and dissection of tissue.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Walker

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012598